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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/548,228	11/02/83	REDDY V	

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EXAMINER	
GIESSER, J	
ART UNIT	PAPER NUMBER
127	7

DATE MAILED: 07/26/85

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~_____ days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-41 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-41 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).

10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure.

Applicants invention depends on the use of new plasmids and/or cells. As such a deposit is required for enablement under 35 USC 112. Conditions surrounding the deposit which must be met for enablement are enumerated in MPEP 608.01(p)(C). While it is acknowledged that applicants have made a deposit, it is not clear that all the aforesaid conditions have been met. Assurance of compliance may be in the form of an oath or declaration.

Claims 1-41 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

Claims 1-4, 32 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 23, 27, 28 and 33-35 of copending application serial no. 548,211. Although the conflicting claims are

not identical, they are not patentably distinct from each other because Application '211 teaches hormones in general and FSH particularly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 5-21 and 37-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-19 and 36 of copending application serial no. 548,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application '211 teaches cells producing hormones in general and FSH particularly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 22-31 and 40 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-22 and 29-32 of copending application serial no. 548,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application '211 teaches vectors producing hormones in general and FSH particularly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-35 and 41 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-26 and 37 of copending application serial no. 548,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application '211 teaches the method of producing hormones in general and FSH particularly.

Claims 1, 4, 32 and 36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of copending application Serial No. 696647.

This is a **provisional** double patenting rejection since the conflicting claims have not in fact been patented.

Claims 5-21 and 37-39 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3-7 of copending application Serial No. 696647.

This is a **provisional** double patenting rejection since the conflicting claims have not in fact been patented.

Claims 22-31 and 40 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-10 of copending application Serial No. 696647.

Claims 33-35 and 41 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 11-14 of copending application Serial No. 696647.

This is a **provisional** double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 5-9, 12-14, 16-17, 19, 22, 29, 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6-9, 12-14, 16, 17, 19, 22, 34 and 35 are indefinite in their recitation of a "subunit" of a protein, as it is not clear what this includes. Claims 5 and 33 are indefinite in the recitation of "in part" and a "portion" of the hormone without further characterization. Claims 1 and 5 contain improper Markush language. Applicant should substitute "selected from the group consisting essentially of..." Claim 29 and contains a typographical error "CL27".

Claims 8 and 9 are rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 8 appears to claim the identical cell as claimed in claim 7. Claim 9 appears to conflict with

claim 7 rather than to further limit it, as claim 7 requires the second submit to be encoded by the second vector, and claim 9 requires the second submit to be encoded by the first vector.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 32 and 36 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Fiddes et al 1980.

Fiddes et al teach that HCG, LH, and FSH are all known hormones. The hormones taught by applicant do not appear different from those of Fiddes et al, they are either inherently present or are obvious over Fiddes et al.

Claim 33 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fiddes et al (1979).

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

> patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 5-12, 16, 18, 21-24, 34, 35, and 37-41 are rejected under 35 U.S.C. 103 as being unpatentable over Cohen et al.

Cohen et al teach that one or more polyamino acids can be cloned in a recipient cell by recombinant techniques. The vector can be a plasmid or a virus and products produced include various hormones including FSH, LH and HGC. Use of more than one vector per cell is envisioned, as plasmids used are high copy number.

Claims 13-15, 17, 19, 20, and 25-31 are rejected under 35 U.S.C. 103 as being unpatentable over Cohen et al, Moriarty et al, Reddy et al, Hamer et al and Sarver et al.

Generalized cloning techniques, including the introduction of more than one gene into a single host cell is known, as taught by Cohen et al. Particular promoter sequences particular promoter sequences used by

applicant to control the production of the foreign polypeptides are also known in the art: SV late promoter (Moriarty et al), SV early promoter (Reddy et al), mouse metallothionein promoter (Hamer et al). Vetors such as bovine papilloma virus are also commonly used to transform eukaryotic cells (Sarver et al.) Thus, it would be obvious to one of ordinary skill in the art to clone one chain of the protein by placing under the control of a first known promoter, and to clone the second chain of the protein by placing under control of a second promoter. In combining these known elements, each continue to function in its known manner to produce a known and expected result, and their placement on a vector(s) is but an arbitrary choice of experimental design.

The Celltech application is included as of interest.

Any inquiry concerning this communication should be directed to Joanne M. Giesser at telephone number 703-557-3920.

Giesser:ce

7-13-85

THOMAS C. WOLMAN
SUPERVISORY PATENT EXAMINER
ART UNIT 127